DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

JAN 10 2017

Mr. David Westlin
Senior Director. Regulatory Affairs and Quality Assurance
Arizant Healthcare, Incorporated
10393 West 70th Street
Eden Prairie, Minnesota 55344

Re: K060939
Trade/Device Name: Ranger Irrigation Fluid Warming System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LGZ
Dated: April 3, 2006
Received: April 6, 2006

Dear Mr. Westlin:

This letter corrects our substantially equivalent letter of June 26, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809]), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K060939

Indications for Use

510(k) Number (if known): K060939

Device Name:

Ranger Irrigation Fluid Warming System

Indications For Use:

The Ranger Irrigation Fluid Warming System is intended to warm irrigation fluids.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...esiology, General Hospita...
...Dental Devices

K060939

JUN 26 2006

510(k) Summary of Safety & Effectiveness

This 510(k) Summary of Safety & Effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92. The device is a Class II device called the Ranger® Irrigation Fluid Warming System.

Submitter

Arizant Healthcare Inc.
10393 West 70th Street, Eden Prairie, MN 55344

Date Prepared

April 3, 2006

Trade/Proprietary Name

Ranger® Irrigation Fluid Warming System

Common/Usual Name

Irrigation Fluid Warmer

Classification Name

Warmer, Irrigation Solution

Predicate Devices

Arizant Healthcare Inc. Bair Hugger Blood/Fluid Warmer (K973741)
Arizant Healthcare Inc. Bair Hugger Patient Warming System (K933726)
Smiths Level 1 IR-600 Normothermic Irrigating Set (K873435)

Description of Device

The Ranger Irrigation Fluid Warming System consists of a warming device and an irrigation fluid warming disposable set. The warming device consists of the electronic control circuitry and aluminum plates contacted by heating elements. The irrigation disposable sets are an integral component of the total fluid warming system.

One standard irrigation fluid warming disposable set is available. The irrigation sets include a warming cassette (heat exchanger), tubing, connectors, flow chamber with float, and clamps. The warming cassette fits inside a slot in the warming device; liquids are warmed as they pass through it.

Intended Use

The Ranger Irrigation Fluid Warming System is intended to warm irrigation fluids.

Comparison of the Technological Characteristics of the New Device and Predicate Devices

The Ranger® Irrigation Fluid Warming System is substantially equivalent to the Bair Hugger Blood/Fluid Warmer (K973741), Bair Hugger Patient Warming System (K933726), and Level 1 IR-600 Normothermic Irrigating Set (K873435).

Comparison of Technological Features

Features	Ranger Irrigation Fluid Warmer	Bair Hugger Blood/Fluid Warmer	Bair Hugger Patient Warming System	Level 1 IR-600 Normothermic Irrigation Set
Flow rates	KVO-650 mL/min[1]	KVO-500 mL/min	KVO-3,000 mL/hr	KVO-650 mL/min[1]
Method of operation	Metal plate heated by electrical resistance; disposable cassette contacts plates	Metal plate heated by electrical resistance; disposable cassette contacts plates	The warming loop sits within the Bair Hugger air hose. Warm air heated to 43°C flows through the air hose, circulating around the single-lumen warming loop.	Fluids are warmed through the use of a sealed heat exchanger through which a recirculating solution flows.
Electronics	PID-controlled	PID-controlled	Warming unit uses Bair Hugger Model 500 and 750 series to provide heat.	Uses water bath technology and PID-controlled electronics
Temperature Control	Electronically Controlled	Electronically Controlled	Electronically Controlled	Electronically Controlled
Alarms	Audible and visual over and under temperature; alarms activate when temperature is at 33°C and at 49°C.	Audible and visual over and under temperature; alarms activate when temperature is at 33°C, at 43°C, and at 46°C.	Audible and visual over temperature alarms activate when temperature is at 53°C.	Audible and visual over temperature alarms activate when temperature is at 43.9°C.

Discussion of Nonclinical Studies and Clinical Tests

Not applicable.

Conclusion

The Ranger Irrigation Fluid Warming System has similar technological characteristics, components, and materials, and the same intended use as devices currently on the market. Therefore, because of the similarities to the predicate devices, Arizant Healthcare believes this new device does not raise any new safety or effectiveness issues.

Contact

David Westlin
Senior Director, Regulatory Affairs and Quality Assurance, Arizant Healthcare Inc.

[1] With scope attached (flow rates may vary due to bag height and brand of scope).